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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,426	11/13/2001	Helle Woldike	5565.214-US	3262

7590 08/28/2002

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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 08/28/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application N .

10/044,426

Applicant(s)

WOLDIKE ET AL.

Examiner

Maria B. Marvich

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### DETAILED ACTION

Claims 1-5 and 7-10 are pending in the application.

This Office action is in response to the amendment and the Terminal Disclaimer filed 8/9/02.

#### *Response to Amendment*

The rejection of claims 1-4 and 7-10 under the judicially created doctrine of obviousness-type double patenting has been withdrawn in light of Applicant's submission of a proper Terminal Disclaimer.

#### *Response to Arguments*

On pages 4-6, Applicant traverses the rejections under 35 U.S.C. 112, first paragraph. Applicant contends that the applicant had possession of the claimed invention i.e. a method for expression of Factor VII in the context of a mammalian cell that also expresses Kex 2 enzymatic activity. Applicant contends that the claims are not directed to a family of proteins having Kex 2 enzymatic activity and that the identification and/or creation of proteins having Kex 2 activity would have been routine for those of ordinary skill in the art.

The rejection of the instant application under 35 U.S.C. 112, first paragraph stands as rejected as containing subject matter not described in the specification in such a way as to reasonably convey that the inventor(s) had possession of the claimed invention (Written Description). The claimed invention is drawn to a method for producing Factor VII comprising cultivation of a mammalian cell line comprising DNA sequences of a yeast-derived endoprotease having Kex2 enzymatic activity and of Factor VII.

Applicants were in possession of a method for expression of Factor VII in the context of a mammalian cell that also expresses Kex 2 enzymatic activity. However, the claims as written read on a method for expression of Factor VII in the context of a mammalian cell that also expresses a yeast-derived endoprotease having Kex 2 enzymatic activity. In the specification a Kex 2 like endoprotease is described as a yeast endoprotease with an amino acid sequence which has a degree of homology to the amino acid sequence of full length kex2 of at least 50% and may differ by insertion or deletion of one or more amino acid residues and/or substitution of one or more amino acid residues in the natural sequence by different amino acid residues. In its broadest sense this claim does read on a family of proteins having Kex 2 activity. The disclosure of Kex 2, two C-terminally truncated derivatives of Kex2 and a Kex 2 with the addition of an ER specific retention signal hardly constitute written description for the identification of any endoprotease with Kex 2 activity. Applicant's arguments that the identification and/or creation of proteins having Kex 2 activity would have been routine for those of ordinary skill in the art are not germane to the written description rejection. The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics such as structure or other physical and/or chemical properties, by functional characteristics couple with a known or disclosed correlation between function and structure or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. Given the lack of written description for the recited DNA sequences and given the absence of an art recognized or disclosed correlation between the structure of the recited enzyme

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and their function, it is maintained that the skilled artisan would not conclude that applicant was in possession of yeast-derived endoproteases having Kex 2 enzymatic activity.

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

#### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kay Pinkney, whose telephone number is (703) 305-3553.



Maria B Marvich, PhD  
Examiner  
Art Unit 1636

August 25, 2002

DAVID GUZO  
PRIMARY EXAMINER  
